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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/737,185	BOWMAN ET AL.
	Examiner	Art Unit
	Yelena G. Gakh, Ph.D.	1743

S.C.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2004 and 26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Declaration under Rule 1.131 filed on 07/12/04 and Supplemental Response filed on 07/26/04 are acknowledged. Claims 1-44 are pending in the application.

MPEP: 715 [R-2] Swearing Back of Reference — Affidavitor Declaration Under 37 CFR 1.131

2. "SITUATIONS WHERE 37 CFR 1.131 AFFIDAVITS OR DECLARATIONS ARE INAPPROPRIATE:

An affidavit or declaration under 37 CFR 1.131 is not appropriate in the following situations: (B) Where the reference U.S. patent or U.S. patent application publication claims the same patentable invention. See MPEP § 715.05 for a discussion of "same patentable invention " and MPEP § 2306".

"715.05 [R-2] **U.S. Patent or Application Publication Claiming Same Invention**

When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, *must be by way of 37 CFR 1.608 instead of 37 CFR 1.131.* If the reference is claiming the same invention as the application and its publication date is less than 1 year prior to the presentation of claims to that invention in the application, this fact should be noted in the Office action. *The reference can then be overcome only by way of interference*. See MPEP §§ 2306-2308".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All independent claims recite "a diagnostic specimen system comprising a population of biomedical specimen collection vessels" with the members of the population located in three different locations (a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory). It is not clear, how does the location of the vessels at different facilities limit their structure? Do the vessels at the distribution station structurally differ from the vessels at the testing laboratory? If their structure is the same, then it is not clear, what is the patentable value of this limitation? Moreover, it is not clear, if the same vessels should always be present at these particular locations, or these vessels are moving from one place to another? If the vessels are moving and changing their location, then how can such system be definite? Besides that, the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.

The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after "wherein" does not bear any patentable weight.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 36-41 and 44** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129B1).

Petrick teaches a method and business form for establishing a chain of custody, which comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206). This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and

management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57).

7. **Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are

recited in the claims indicated above. "A population of " biomedical specimen collection with "members" located at various locations of the specimen path is an intrinsic feature of the invention.

The methods for electronically storing information and recording information, recited in claims 18, 19 and 21 are inherently disclosed in the specification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 5, 8 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick.

Although Petrick did not specifically disclose storing data including the identity of a supplier of the container (vessel?) and its product information, it would have been obvious for anyone of ordinary skill in the art to include this information along with other data in Petrick's specimen system, because vessels (containers) from different suppliers may vary, and therefore such information is important for handling them properly, and because information on a supplier is always conventionally provided with products.

12. **Claims 16, 17, 20, 38, 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick in view of Hoffman et al. (US 5,613,012).

Although Petrick does not particularly teach encoding electronic signature in the electronic tag, she specifically indicates "tester's signature" in form 102, Fig. 3B.

Since Petrick indicated that all forms can be filled manually or electronically, it would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman for securing electronic transactions, because this is an obvious improvement over hand-written document and because electronic submission of the forms suggested by Petrick assumes electronically encoded signature.

13. **Claims 2 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

14. **Claims 1, 6-7, 9-10, 14-15, 18-19 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney (US 5,777,303) in view of Bowman (US 5,135,313).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered.

Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

The methods for electronically storing information and recording information, recited in claims 18, 19 and 21 are inherently disclosed in the specification.

Berney does not specifically disclose that the vessel is a tamper-indicating vessel.

Bowman discloses a chain-of-custody tamper-indicating bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

15. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, as applied to claims 1, 6-7, 9-10, 14-15, 18-19 and 21 above, and further in view of Stevens et al. (EP 1,004,359 A2).

Berney in view of Bowman do not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his

container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

16. **Claims 5 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman and Stevens, as applied to claims 3 and 4 above, and further in view of the prior art disclosed by Leuenberger (US 5,314,421).

Although Stevens indicated that the label might contain product information, he is silent regarding information on a supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and because information on a supplier is always conventionally provided with products.

17. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, RD 421048 A, Stevens and Leuenberger.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). He does not specifically indicate the container to be tamper-indicating. Bowman discloses tamper-indicating sealed container for transporting specimen to a remote location, which makes it obvious for anyone of ordinary skill in the

art to apply the same tamper-indicating seal to Berney's container for the same reasons indicated by Bowman, i.e. to prevent intentional tampering of the seal.

Berney in view of Bowman do not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

Berney in view of Bowman and RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Berney, Bowman, RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage

solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to modify Berney-Bowman's container by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A; adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container; and adding information on identity of suppliers as indicated by Leuenberger, because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container.

18. **Claims 16, 20 and 38-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, as applied to claims 1, 6-7, 9-10, 14-15, 18-19 and 21 above, and further in view of Fukuzaki (US 5,948,103).

Berney in view of Bowman do not disclose an encoded electronic signature of a donor of a toxicological specimen stored in the tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skills in the art to employ Fukuzaki's electronic security system, including encoded electronic signature security system, for Berney-Bowman's container when it is used for toxicological analysis, because the information contained in Berney-Bowman's electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case.

19. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki and Coli et al. (US 6,018,713).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). He does not specifically indicate the container to be tamper-indicating. Bowman discloses tamper-indicating sealed container for transporting specimen to a remote location, which makes it obvious for anyone of ordinary skill in the art to apply the same tamper-indicating seal to Berney's container for the same reasons indicated by Bowman, i.e. to prevent intentional tampering of the seal.

Berney in view of Bowman do not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

Berney, Bowman and RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Berney-Bowman-RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

Berney, Bowman, RD 421048 A, Stevens and Leuenberger do not disclose encoded electronic signature of the donor stored in the electronic tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skills in the art to modify Berney-Bowman's container by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A; adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container; adding information on identity of suppliers as indicated by Leuenberger, because, first

this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container; and adding an encoded electronic signature of the donor of the toxicological specimen, because the information contained in improved Berney-Bowman's electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case.

Response to Arguments

20. Applicant's arguments filed on 06/17/04 have been fully considered but they are not persuasive. The Declaration under Rule 1.131 is improper, since the present application claims substantially identical invention to the one disclosed in US 6,535,129 B1, with the filing date less than three months later than the filing date of the patent. Therefore, all rejections over Petrick remain the same as was established in the previous Office action.

Regarding rejections over Barney. As the examiner indicated in subparagraph 4 of the present Office action, as well as in the previous Office action, location of the members of "the population of the collection vessels" does not bear any patentable weight, as it does not limit the structure of the vessels, which is the essence of the instant invention. The vessels can be moved from one location to another without changing their structure. Moreover, if the specific vessels are associated with specific locations, where they should be present all the time, it is not clear, how such system can work and what would be its function. If, as the Applicants suggested, one vessel is always present at a vessel distribution facility, another – at a specimen collection facility, and the third – at a specimen testing laboratory, does it mean that they are not moved and they cannot be present in any transportation means?

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
11/14/04